IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION
No. 5:20-CV-536-FL

BECTON, DICKINSON AND COMPANY, Plaintiff, v. BIOMEDOMICS, INC., Defendant.	**BIOMEDOMICS, INC.'S FIRST AMENDED ANSWER AND COUNTERCLAIM**

COMES NOW Defendant BioMedomics, Inc. ("BioMedomics"), by and through counsel and pursuant to Rule 15(a)(2) of the Federal Rules of Civil Procedure, and provides its First Amended Answer and Counterclaim to Plaintiff Becton, Dickinson and Company's ("BD") Complaint in this action and shows the Court the following:

ANSWER TO COMPLAINT

PARTIES

1. BioMedomics admits the allegations of this paragraph on information and belief.

2. BioMedomics admits the allegations of this paragraph.

3. BioMedomics admits the allegations of this paragraph on information and belief.

4. BioMedomics admits the allegations of this paragraph.

JURISDICTION AND VENUE

5. BioMedomics admits the allegations of this paragraph.

6. BioMedomics admits the allegations of this paragraph.

FACTS

7. BioMedomics admits the allegations of this paragraph.

8. The referenced document speaks for itself as a matter of fact and law, and therefore no response is required. BioMedomics denies any allegation of this paragraph inconsistent therewith.

9. BioMedomics admits the allegations of this paragraph.

10. As to what BD "agreed," the referenced document speaks for itself as a matter of fact and law, and therefore no response is required. BioMedomics denies any allegation of this paragraph inconsistent therewith. As to what BD "understood," BioMedomics lacks knowledge and information sufficient to form a reasonable belief as to the truth of the allegations of this paragraph. To the extent that further response is required, the allegations are denied.

11. The referenced document speaks for itself as a matter of fact and law, and therefore no response is required. BioMedomics denies any allegation of this paragraph inconsistent therewith.

12. The referenced document speaks for itself as a matter of fact and law, and therefore no response is required. BioMedomics denies any allegation of this paragraph inconsistent therewith.

13. The referenced document speaks for itself as a matter of fact and law, and therefore no response is required. BioMedomics denies any allegation of this paragraph inconsistent therewith.

14. BioMedomics admits the allegations of subparagraphs (a), (b), and (d) of paragraph 14 of the Complaint. Except as expressly admitted herein, BioMedomics denies the remaining allegations of paragraph 14 in their entirety.

15. BioMedomics denies the allegations of this paragraph.

16. BioMedomics denies the allegations of this paragraph.

17. The referenced document speaks for itself as a matter of fact and law, and therefore no response is required. BioMedomics denies any allegation of this paragraph inconsistent therewith.

18. BioMedomics admits the allegations of this paragraph on information and belief.

19. BioMedomics admits the allegations of this paragraph.

20. BioMedomics admits the allegations of this paragraph.

21. BioMedomics lacks knowledge and information sufficient to form a reasonable belief as to the truth of the allegations of this paragraph. To the extent that further response is required, the allegations are denied.

22. BioMedomics admits the allegations of this paragraph.

23. BioMedomics admits the allegations of this paragraph.

24. BioMedomics admits the allegations of the first sentence of this paragraph. BioMedomics denies the allegations of second sentence of this paragraph.

25. BioMedomics admits that BD sent a notice on August 14, 2020 stating that it did not intend to continue its relationship with BioMedomics and demanded a full repayment of its prepayment for the Product. Except as expressly admitted, BioMedomics denies the allegations of this paragraph.

26. BioMedomics admits the allegations of this paragraph.

FIRST CAUSE OF ACTION
(BREACH OF CONTRACT)

27. BioMedomics hereby realleges its responses to paragraphs 1 through 26 above as if fully set forth herein.

28. The allegations of this paragraph constitute legal conclusions to which a response is not required and assume allegations in prior paragraphs which have been denied. To the extent that further response is required, BioMedomics denies the allegations of this paragraph.

29. The referenced document speaks for itself as a matter of fact and law, and therefore no response is required. BioMedomics denies any allegation of this paragraph inconsistent therewith.

30. BioMedomics denies the allegations of this paragraph.

31. BioMedomics denies the allegations of this paragraph.

32. BioMedomics denies the allegations of this paragraph.

SECOND CAUSE OF ACTION
(UNJUST ENRICHMENT)

33. BioMedomics hereby realleges its responses to paragraphs 1 through 32 above as if fully set forth herein.

34. BioMedomics denies the allegations of this paragraph.

35. BioMedomics denies the allegations of this paragraph.

BioMedomics denies all allegations in BD's Complaint not expressly admitted in the paragraphs above.

FIRST AFFIRMATIVE DEFENSE

BioMedomics is immune from suit and liability with respect to BD's claims pursuant to the Public Readiness and Emergency Preparedness Act, 42 U.S.C. § 247d-6d.

SECOND AFFIRMATIVE DEFENSE

BD fails to state a claim against BioMedomics upon which relief can be granted.

THIRD AFFIRMATIVE DEFENSE

BD may not recover of BioMedomics as BioMedomics has fully performed all of its contractual and common law duties to BD regarding the Product.

FOURTH AFFIRMATIVE DEFENSE

BD's claims are barred in whole or in part by the doctrine of estoppel and detrimental reliance.

FIFTH AFFIRMATIVE DEFENSE

BD failed to mitigate its damages through express refusal to participate in cover sales of the Product.

SIXTH AFFIRMATIVE DEFENSE

BD's claims are barred in whole or in part by the doctrine of impossibility of performance.

SEVENTH AFFIRMATIVE DEFENSE

BD's claims are barred in whole or in part by the doctrine of unclean hands.

EIGHTH AFFIRMATIVE DEFENSE

BD's claims are barred in whole or in part by its repudiation of the contract in question.

NINTH AFFIRMATIVE DEFENSE

BD's claims are barred in whole or in part by the reason of setoff.

TENTH AFFIRMATIVE DEFENSE

BD's breach of contract claims are barred by the failure of performance and the failure of consideration.

ELEVENTH AFFIRMATIVE DEFENSE

Plaintiff's claims are barred by Plaintiff's own breach of the contract in question.

TWELFTH AFFIRMATIVE DEFENSE

BD's claims are barred in whole or in part by the doctrine of waiver.

COUNTERCLAIM

COMES NOW BioMedomics, Inc. ("BioMedomics"), Defendant in the above-styled action, and pursuant to Rule 13 and Rule 15(a)(2) of the Federal Rules of Civil Procedure, to set forth its Counterclaim against Plaintiff Becton, Dickinson and Company, Inc. ("BD"), showing this Honorable Court as set forth herein.

JURISDICTION AND VENUE

1. This Court has jurisdiction over the subject matter of this action and the parties hereto.

2. Venue is proper in this Court for this Counterclaim.

3. All conditions to the bringing of this action have met, waived, or otherwise satisfied.

FACTS

4. BD is a global medical technology company based in New Jersey that sells medical devices, instrument systems, and reagents.

5. BioMedomics is a company that specializes in the development of point-of-care clinical diagnostics to create life-saving diagnostic solutions and address global healthcare needs.

6. In December 2019, a novel (new) coronavirus known as SARS-CoV-2 ("COVID-19") was first detected in Wuhan, Hubei Province, People's Republic of China.

7. Since its detection, COVID-19 has infected many individuals around the globe. On or about March 11, 2020, the World Health Organization determined COVID-19 spurred a global pandemic.

8. Knowledge of prior infection is epidemiologically important and represents a significant unmet need in the management of the COVID-19 pandemic.

9. To address this significant unmet need in the United States and around the world, BioMedomics developed and launched its IgM/IgG assay (the "Product") able to detect COVID-19 antibodies for a prolonged period of time after disease resolution, enabling identification of prior infection.

10. Recognizing the importance of tracing the spread of COVID-19, the United States Food and Drug Administration ("FDA") issued policy guidance on or about March 16, 2020 that it would not object to production and distribution of tests designed to detect COVID-19 provided certain conditions were met.

11. Specifically, under the March 16, 2020 guidelines, the FDA permitted the manufacture, distribution, and use of serology tests without Emergency Use Authorization ("EUA") if the tests had been self-validated; notice was given to consumers that FDA had not reviewed the tests and test results should not be used as a sole basis for diagnosing or excluding COVID-19; and an EUA request was submitted to the FDA within 15 business days.

12. From March 16, 2020 to March 26, 2020, BD reached out to BioMedomics to investigate whether it wanted to purchase the Product. This included inspection of BioMedomics and its affiliate's facilities, receiving from BioMedomics Product specification information, and reviewing samples of the Product for evaluation.

13. Ultimately, the parties signed a nonbinding Term Sheet on March 26, 2020, calling for a definitive distribution agreement (the "Term Sheet"). The Term Sheet only covered units of the Product intended for sale in the United States (the "Import Product"). However, the parties also contemplated that BD and BioMedomics would negotiate in good faith distribution of the Product in other areas of the world (the "Export Product") once they established a course of dealing.

14. On April 2, 2020 at 2:30 p.m., BioMedomics' Chief Executive Officer Frank Wang ("Wang") met with authorized BD representatives Troy Hopps ("Hopps"), then BD's Business Group Leader for Point of Care Integrated Diagnostic Solutions, and Dave Hickey ("Hickey"), President of Integrated Diagnostic Solutions for BD, via conference call. During that meeting, BD requested increased production of the Import Product, distribution rights to sell Export Product in other countries, and that all April and May units of the Import Product be shipped to BD.

15. At BD's direction, BioMedomics produced tests labeled with a barcode identifying the Product as belonging to BD. This barcode marked each unit of product as BD inventory and enabled BD to track sale and distribution of units through its unique system. An example of the barcodes affixed to the Product and bearing BD's unique reference number (256083) is attached to this First Amended Counterclaim as Exhibit A.

16. Discussions for sale of Export Product continued through April 2020. On April 27, 2020, BD sent BioMedomics estimated volumes and pricing for Export Product and proposed purchasing 1.5 million units of Export Product per month over a year at a price of $6.00. BD also stated that it "would be responsible for all regulatory registrations required to sell the product in each of the countries" outside the United States. True and correct copies of some of the parties' correspondence regarding purchase of the Export Product, as well as a forecast of the units of Export Product BD anticipated purchasing, is attached to this First Amended Counterclaim as Exhibit B.

17. On April 28, 2020 the parties' representatives met again to discuss production. BD indicated that it wanted 1,500,000 units of Import Product and 1,000,000 units of Export Product in June. BD represented to BioMedomics that it would order 2,000,000 units of Import Product

and 1,500,000 units of Export Product for each month beginning with July. BioMedomics agreed to these production requests.

18. By no later than May 1, 2020, BD and BioMedomics agreed on the sale price of $6.50 per unit of Export Product (with BD to arrange the shipping from manufacture site), along with the other terms set out in Hopps' email to Wang date April 27, 2020. *See* Exhibit B.

19. BD, through Hopps, later acknowledged the "pricing already agreed for . . . outside the US ($6.50)" in an email to BioMedomics on June 7, 2021 discussing regulatory approval, quantities, shipment, and pricing of Export Product with BioMedomics. A true and correct copy of this email is attached to this First Amended Counterclaim as Exhibit C.

20. On May 4, 2020, the FDA modified its guidance, requiring higher performance sensitivity for serology tests. The Product did not meet this new requirement.

21. Following this change in regulatory policy, BioMedomics and BD discussed and agreed to withdraw the EUA application for the first generation of the Product and submit an EUA application for the second generation of the Product.

22. BioMedomics internally tested the second generation the Product and determined that it met the FDA's new requirements for an EUA. BD completed its own review of the Product and also was satisfied that the second generation of the Product met the FDA's requirements.

23. In the meantime, BioMedomics prepared to manufacture and ship BD's purchased units of the Product.

24. On May 26, 2020, Hopps and Wang, discussed shipment of the Export Product to BD. In addition to the quantities of Import Product, BD again requested that BioMedomics procure 1,000,000 units of second generation Export Product for BD in June. A true and correct copy of BD's correspondence with BioMedomics memorializing the parties' agreements regarding

quantities of Export Product to be produced is attached to this First Amended Counterclaim as Exhibit D.

25. Upon information and belief and based on requests and statements by BD's authorized representatives, during late May 2020 BD's management team asked BioMedomics to produce and ship tests to BD so that BD would be more likely to meet its second quarter financial goals (i.e., reports compiled as of the end of June 2020). At the time of these requests and statements, BD knew that BioMedomics did not have an EUA but accepted the risk that BioMedomics would not obtain approval in hope that BD could meet its performance goals.

26. BD also requested BioMedomics provide 1,500,000 units of second generation units of the Export Product per month from July to September. *See* Exhibit D.

27. BD represented to BioMedomics that BD would issue purchase orders for these units of the Export Product. *See* Exhibit D.

28. On information and belief, BD's purchase orders are subject to standard terms and conditions, including that its contracts are governed by New Jersey law. The parties intended these standard terms and conditions to apply to purchases of the Export Product.

29. In response to BD's requests, BioMedomics confirmed to BD in writing that BioMedomics agreed to produce the requested amount of the Product for BD. *See* Exhibit D.

30. BD's Trade Compliance Specialist provided BioMedomics information for delivery of the Product in Europe on or about May 27, 2020.

31. BD also reached out to BioMedomics to set a shipment schedule for the units of the Import Product and Export Product. BD then followed up with BioMedomics on or about May 31, 2020 on setting a shipment schedule.

32. BioMedomics responded to BD's inquiry, agreeing to send 1,000,000 units of Export Product to BD in Europe by mid-July, with an additional weekly deliveries of the Product beginning thereafter for both the United States and outside the United States markets.

33. Because BD and BioMedomics were both merchants trading in diagnostic products, and due to the significant, immediate demand for the Product created by the COVID-19 pandemic, the Parties agreed upon sale of the Export Product without the execution of typical contract documentation which had been completed for the Import Product.

34. On May 29, 2020, the parties discussed transportation and materials costs for the Export Product. One week later, BD requested that BioMedomics ship the Export Product to the European Union.

35. Ultimately, BioMedomics produced three distinctly labeled products: 1) its standard serology assay sold by BioMedomics outside the United States, 2) BD's Import Product, and 3) BD's Export Product. Examples of the labels for each of these serology assays are attached to this First Amended Counterclaim as Exhibit E.

36. In accordance with its agreements with BD, from April 28, 2020, to July 10, 2020, BioMedomics procured a total of 2,500,000 units of Export Product for BD.

37. At no point has BD paid for the Export Product that it purchased.

38. On or about August 14, 2020, BD sent a letter repudiating BD's agreements with BioMedomics. The letter, which purported to terminate the parties' relationship, was grounded solely upon the absence of an EUA for distribution of the Import Product. However, BD did not offer any reason that it could not sell or distribute the Export Product. In fact, BD expressly assumed responsibility for registration of the Export Product in countries outside the United States.

39. Because of BD's expansive monthly requirements for delivery of the Product, BioMedomics bought significant amounts of production materials to supply the Product to satisfy BD's requirements.

40. The Export Product is not suitable for sale and distribution to anyone other than BD.

41. BioMedomics cannot resell BD's Export Product to another buyer in the ordinary course of business because BD's barcodes and other packaging requirements for the Export Product were specially designed to interface with BD's unique inventory control system and hold the product out as BD's product. Upon information and belief, BioMedomics cannot sell serology tests to a customer bearing another company's reference number in the ordinary course of business.

42. Furthermore, BioMedomics is not able to repackage the Export Product purchased by BD because doing so is cost-prohibitive. Upon information and belief, BioMedomics would lose money repackaging and reselling BD's Export Product.

FIRST CAUSE OF ACTION
(BREACH OF CONTRACT)

43. BioMedomics realleges the foregoing paragraphs above as if fully set forth herein.

44. Where the Parties contracted for the sale of goods, North Carolina's choice of law statute under Article Two of the Uniform Commercial Code determines the law applicable to BioMedomics' claims.

45. New Jersey bears the most significant relationship to the sale of the Product to BD, based on the terms of sale the parties in their course of dealing had agreed to in previous purchases. Thus, New Jersey law governs BioMedomics' counterclaim.

46. Through its course of dealing with BioMedomics in or around April to May 2020, and as confirmed by BD's representative Hopps in writing, BD offered to purchase 1,000,000 units

of Export Product in June 2020. BD also confirmed in writing it would purchase 1,500,000 units of Export Product per month in July, August, and September.

47. In its course of dealing with BioMedomics in late April and early May 2020, and as later confirmed by BD's representative Hopps in writing, BD expressly agreed upon a price of $6.50 per unit of Export Product.

48. BioMedomics, through Wang, accepted BD's offers shortly thereafter.

49. Through their course of dealing, usage of trade, and course of performance, and in light of significant, urgent global demand for COVID-19 serology tests, BD and BioMedomics understood that BioMedomics would immediately begin to produce the Export Product for BD.

50. BioMedomics performed under the contract, procuring a total of 2,500,000 units of Export Product for BD.

51. BD breached the contract by refusing to pay BioMedomics for the Export Product it purchased, repudiating its relationship with BioMedomics on August 14, 2020 and wrongfully refusing to take delivery of the Export Product.

52. BD's breach of contract proximately caused BioMedomics loss in an amount in excess of $75,000.00 to be proven at trial.

SECOND CAUSE OF ACTION
(PROMISSORY ESTOPPEL)

53. BioMedomics realleges the foregoing paragraphs above as if fully set forth herein.

54. BD made a clear and definite promise to purchase the Export Product with the intent of distributing the Export Product outside the United States.

55. BD made its promise with the expectation that BioMedomics would rely upon it and rapidly develop and acquire the Export Product for sale to BD.

56. As two merchants seeking to sell the Product in a rapidly expanding market for products aiding management of the COVID-19 pandemic, and where BD had already purchased significant quantities of the Product from it, BioMedomics reasonably relied upon BD's promise to produce a total of 2,500,000 units of the Export Product.

57. By refusing to pay BioMedomics for the 2,500,000 units of the Export Product, BD has caused BioMedomics to incur a definite and substantial detriment, including the purchase of significant amounts of production materials to supply the Export Product to satisfy BD's requirements. Such detriment was in excess of $75,000.00.

PRAYER FOR RELIEF

WHEREFORE, Defendant respectfully prays for relief as follows:

1. That the action be tried by jury on all issues so triable;

2. That BD have and recover nothing from BioMedomics;

3. That BioMedomics have and recover damages in excess of $75,000.00 upon its Counterclaim against BD, in an amount to be proven at trial;

4. That the Court enter an award against BD for prejudgment and post judgment interest as allowed by law;

5. That the costs of this action, including reasonable attorneys' fees, be taxed against BD as allowed by law; and

6. That BioMedomics have such other and further relief as the Court may deem just and proper.

Respectfully submitted this the 6th day of July, 2021.

/s/ Walter L. Tippett, Jr.
Walter L. Tippett, Jr.
N.C. State Bar No. 22357
Email: wtippett@brookspierce.com
William A. Robertson
N.C. State Bar No. 53589
E-mail: wrobertson@brookspierce.com
BROOKS, PIERCE, MCLENDON,
HUMPHREY & LEONARD, LLP
1700 Wells Fargo Capitol Center
150 Fayetteville Street
Raleigh, North Carolina 27601
Tel. (919) 839-0300
Fax (919) 829-0304
Counsel for Defendant/Counterclaim Plaintiff BioMedomics, Inc.